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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,594	11/14/2003	Mohamed Attawia	3518.1012-005	3230
21005 7590 09/10/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER STANDLEY, STEVEN H	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,594

Applicant(s)

ATTAWIA ET AL.

Examiner

Steven H. Standley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-18, 20-24 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-18, 20-24 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 6/14/07 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Priority

2. Below are Examiner's arguments in the prior office action:

"The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/456,948, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The Examiner has considered Applicant's arguments concerning priority and finds that while application 10/456,948 contains prophetic teachings of treatment with mesenchymal cells, the prior art cited (Sakai et al., 2003) in rejections under both 35 USC § 112, 1st paragraph, and 35 USC § 103 provides the only enabled aspects of the instant invention. In other words, the claims are only enabled to the extent that the prior art teaches the instant invention. Thus, the earliest time at which the invention can be considered enabled by the prior art is at application 10/714,559, filed 11/13/03."

Applicant argues the prophetic passage on page 21, line 28 to page 22, line 9 of the application 10/456,948 discloses administration of autologous mesenchymal cells in accordance with the instantly claimed invention. This is not found persuasive because the method taught is a method of administration of a **composition** comprising firstly, a

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cytokine antagonist (see page 20, bottom), and secondly a laundry list of other generic compounds such as hormones, glycoproteins, carbohydrates, and in some embodiments mesenchymal stem cells. It does not teach sole administration of mesenchymal cells. Furthermore, it provides absolutely no enabling support for administration of mesenchymal stem cells other than methods of concentration of cells, which are well known and have nothing to do with treatment.

Applicant cites *in re Wands* and asserts that one of skill in the art could have made and used the invention without undue experimentation. The Examiner first interprets this to be an admission that applicant has no evidentiary or experimental support for the method claimed in the '948 application. Secondly, applicant is reminded that *In re Wands* pertained to the making and using of antibodies, not methods of treating degenerative disc disease with stem cells. One of skill in the art could not devise a method of treating an injury such as a degenerative disk by administration of stem cells without undue experimentation at the time of the '948 application. Therefore *in re Wands* is not relevant and not persuasive with regard to enabling said method with prophetic language.

Objections/Rejections: Withdrawn

Claim Rejections - 35 USC § 112

3. Rejection of claims 1-7, 10-18, 20-24, and 31-32 under 35 USC § 112, 1st, enablement is withdrawn due to applicant's amendments (in particular to limit "growth factors" to TGF-Beta) and arguments.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Rejection of claims 1-3, 5-6, 10-16, 20-24, 31 and 33 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 9/17/06 and 3/12/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues assert the examiner has not applied the Sakai reference dated May, 2003. The examiner agrees. However much of the broad substance of the claims is also disclosed in the Sakai et al 2003 reference.

The applicant also argues that Sakai et al is not available as prior art. This is not the case. The Biomaterials publication of Sakai is dated September 2003 which antedates the applications that are enabling for the method. See arguments under "Priority." Applicant argues also that the instant method is a method of using uncultured

cells and one of ordinary skill in the art would not be motivated to practice the claimed invention with a reasonable expectation of success based on the teachings of Sakai et al. This is not found persuasive because Sakai, in fact, practices a more difficult method in culturing mesenchymal cells solely in order to label them (ie, applicant has not disclosed an easier or more efficient way, it is just that Sakai et al must demonstrate that the therapeutic cells survived and that the method worked) and expand them.

Applicant argues on pages 11-14 of Remarks that the prior art only teaches culturing of mesenchymal stem cells for the purposes of expansion. While expansion gives more cells, immediate transplantation offers the obvious advantage of immediate delivery and treatment.

The motivation to concentrate and administer mesenchymal stem cells is that the procedure would take hours instead days. The expectation of success is, indeed, higher than that demonstrated by Sakai et al because there is less opportunity for contamination in a period of hours instead of days or weeks.

Applicant argues that the method of Sakai et al cannot be used as a therapeutic. This is not found persuasive because Sakai et al demonstrate the effectiveness of the treatment (see abstract of publication, or 'results' section of the annual meeting abstract (submitted in applicant's ids).

Applicant argues on page 15 that the examiner has used impermissible hindsight. This is not found persuasive. Sakai et al had to culture the cells in order to label them and demonstrate the method was effective. Sakai, in fact, is the prior art that enables the instant invention. Applicants have not performed the method of Sakai et al

without expanding the cells by culture. Yet, one skilled in the art, having read Sakai et al, would know that the method would work without culturing the cells.

Applicant also argues on page 15 that culturing the cells would subject them to contamination and exposure to DMEM. This is not found persuasive because applicant has simply pointed out another obvious advantage. Applicants were not required herein to show that the treatment works because Sakai et al already have. Sakai et al had to culture the cells in order to label them to ascertain whether the cells survived. What Applicant has claimed is obvious from Sakai et al.

5. Rejection of claims 1-6, 10-16, 20-24, 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Sakai et al as applied to claims 1-3, 5-6, 10-16, 20-24, and 31 above, and further in view of Tanney et al (1980) is maintained.

Applicant argues that Tanney et al teaches cultured cells which reinforces Applicant's argument that using uncultured cells is novel and non-obvious. This is not found persuasive. Sakai et al teach using autologous cells for administration in the instantly claimed method. Applicant has simply skipped a step that was required for Sakai et al to demonstrate therapeutic value but is not required, precisely because Sakai et al demonstrated it, in the instant method. Tanney et al simply teaches concentration of cells by filtration.

6. Rejection of claims 1-3, 5-7, 10-16, 18, 20-24, and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Sakai et al as applied to claims 1-3, 5-6, 10-16, 20-24, and 31 above, and further in view of Russell et al (May 2003 meeting abstract, in applicant's IDS) is maintained.

Applicant argues the same as the section immediately above. This is not found persuasive for reasons indicated.

7. Rejection of claims 1-3, 5-7, 10-17, 18, 20-24, and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Sakai et al as applied to claims 1-3, 5-6, 10-16, 20-24, and 31 above, and further in view of Russell et al (may 2003 meeting abstract, in applicant's IDS) is maintained.

Applicant argues essentially the same as the above. This is not found persuasive for the reasons indicated.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christina Chan can be reached on (571) 272-0849. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D.

8/31/07



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